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10/552,675	08/15/2006	Daniel Baumgartner	001227/0954	2286
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STROOCK & STROOCK & LAVAN, LLP			MERENI, JAN CHRISTOP L	
180 MAIDEN LANE			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/552,675	BAUMGARTNER ET AL.
	Examiner JAN CHRISTOPHER MERENE	Art Unit 3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on September 10, 2008.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 16-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 16-32 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/0256/06)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application

6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 16-31 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claims 16 and 25 lines 2-3, respectfully), the applicant positively recites part of a human, i.e. "endface to contact at least a portion of an upper vertebra". Thus claims 16-31 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. **Claims 16-17, 23-24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbe et al US 5,776,198 in view of Schonhoffer US 6,015,436.

Regarding **Claim 16**, Rabbe et al discloses an intervertebral implant comprising (as seen in Fig 3): an intervertebral spacer body (#21) having at least an upper endface (upper face of #21, where when implanted between adjacent vertebra would be capable of contacting at least a portion of an upper vertebra) configured to contact at least a portion of an upper vertebra when in an implanted configuration; and at least one end member (#22) including a plurality of spikes (#120) for engaging at least a portion of

the upper vertebra, wherein the at least one end member is slidably movable with respect to the intervertebral spacer body so that the at least one end member is moveable between a first position and a second position wherein when in the first position the plurality of spikes formed on the at least one end member extend beyond the upper endface of the spacer body and when in the second position the plurality of spikes formed on the at least one end member do not extend beyond the upper endface of the spacer body (see Col 5 lines 50-60, where a set screw #24 is used for fixing endplate #22 to the body #21, where the endplate #22 would be capable of being slidably movable against #21 and where the spikes would extend/ not extend beyond the body #21, depending where one would secure the set screw #24 or how far one would want to thread #22 against the body #21).

Rabbe et al also teaches:

in **Claim 17**, fastening means (#24) for securing the end member to the intervertebral spacer body in the first position;

in **Claim 23**, at least one closing plate (#52) adjacent the upper endface.

in **Claim 24**, a lower endface (lower end surface of #21, where when implanted between adjacent vertebra would be capable of contacting the lower portion of the lower vertebra) configured to contact at least a portion of a lower vertebra when in an implanted configuration; and the intervertebral implant further includes a second end member (#22) including a plurality of spikes (#120) for engaging at least a portion of the lower vertebra, wherein the second end member is also slidably movable with respect to the intervertebral spacer body so that the second end member is moveable between a

first position and a second position wherein when in the first position the plurality of spikes (#120) formed on the second end member extend beyond the lower endface of the intervertebral spacer body and when in the second position the plurality of spikes formed on the second end member do not extend beyond the lower endface of the intervertebral spacer body (see Col 5 lines 50-60, where a set screw #24 is used for fixing endplate #22 to the body #21, where the endplate #22 would be capable of being slidably movable against #21 and where the spikes would extend/ not extend beyond the body #21, depending where one would secure the set screw #24).

However, Rabbe et al does not specifically disclose that the end members are non-rotatable movable with the spacer body.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to not have the threads of Rabbe et al, wherein the end member would be capable of non-rotatably slidably movable between a first and second position (where the end member would still be held in place by screw #24), since it has been held that omission of an element and its function in a combination where the remaining elements perform the function as before involves only routine skill in the art. *In re Karlson*, 136 USPQ 184

Furthermore, Schonhoffer discloses a similar device (as seen in Fig 4), where an body and an end member is non-rotatably slidably moveable (see Col 3 lines 35-40), where the components are secured together using a screw (#10 see Col 4 lines 10-13)).

It would also have been obvious to one having ordinary skill in the art at the time the invention was made to remove the threads of Rabbe et al to allow for non-rotatably,

slidable movement as taught by Schonhoffer because non-rotatably, slidable movement applies a known technique to a known device ready for improvement to yield predictable results of adjusting the length between intervertebral implants (see Col 3 line 1-5, and see Col 3 line 35-40).

5. **Claims 18-20, 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbe et al US 5,776,198 and Schonhoffer US 6,015,436, as applied to claim 16 above, and in further view of Castro et al US 6,899,734.

Rabbe et al and Schonhoffer disclose the end member includes a top surface, a bottom surface, an internal bore defining an inner surface for non-rotatably, slidably receiving the intervertebral spacer body therein (as seen in Fig 3 and see above), but does not specifically disclose one or more elastically deformable projections extending from the inner surface, the elastically deformable projections engaging the intervertebral spacer body when the end member is in the first position so that the position of the end member with respect to the spacer body is secured, wherein the one or more elastically deformable projections are hook-type members, the elastically deformable projections are integrally formed with the end member, wherein the intervertebral spacer body includes one or more recesses for engaging the one or more elastically deformable projections

However, Castro et al discloses a similar device (as seen in Fig 3a) with an end member (#40) includes a top surface, a bottom surface, an internal bore (as seen in Fig 3a) and one or more elastically deformable projections (#48) extending from the inner

surface, the elastically deformable projections engaging the intervertebral spacer body when the end member is in the first position so that the position of the end member with respect to the spacer body is secured, wherein the one or more elastically deformable projections are hook-type members, the elastically deformable projections are integrally formed with the end member, wherein the intervertebral spacer body (#12) includes one or more recesses (#23 as seen in Fig 1) for engaging the one or more elastically deformable projections (see Fig 1 and Fig 3a and Col 4 lines 45-53, which disclose hook type members, semi-resilient detents #48, which can easily be snapped into recess #23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rabbe et al to include the deformable projections (#48) and the recess (#23) of Castro et al, as disclosed above because the deformable projections (detents #48) with a corresponding recess is a simple substitution of one known element, known in the art, for another to secure an end plate onto an intervertebral spacer and is an easy way for a surgeon to simply snap the endplate into place (see Col 4 lines 45-53). (The examiner also notes that the holes (#28) of Rabbe et al would also be capable of locking in deformable projections (#48) of Castro et al, if one would so choose to and properly size the projections).

6. **Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbe et al US 5,776,198, Schonhoffer US 6,015,436, and Castro et al US 6,899,734, as applied to Claim 18 above, in further view of Fortier US 6,106,539.

Rabbe et al and Castro et al disclose the claimed invention with a deformable projection, as recited above, but does not specifically disclose the spacer body includes a shoulder for engaging one or more elastically deformable projections.

However Fortier discloses a similar deformable projection (#28c as seen in Fig 7) with a shoulder (#34c) on the body to which it is connecting to.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the spacer of Rabbe et al to include a shoulder (#34c) as taught by Fortier because a shoulder provides a stop means for a detent mechanism (see Col 2 lines 37-39).

7. **Claims 25-26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbe et al US 5,776,198 in view of Schonhoffer US 6,015,436.

Regarding **Claim 25**, Rabbe et al discloses an intervertebral implant (as seen in Fig 3) comprising: an intervertebral spacer body (#21) having an upper endface (upper face of #21, where when implanted between adjacent vertebra would be capable of contacting at least a portion of an upper vertebra) configured to contact at least a portion of an upper vertebra when in an implant configuration and a lower endface (lower face of #21, where when implanted between adjacent vertebra would be capable of contacting at least a portion of an upper vertebra) configured to contact at least a portion of a lower vertebra when in an implanted configuration;

a first end (#22) member including a plurality of spikes (#120) for engaging at least a portion of the upper vertebra;

and a second end member (#22) including a plurality of spikes (#120) for engaging at least a portion of the lower vertebra; wherein the first and second end members are slidably movable with respect to the intervertebral spacer body so that the first and second end members are moveable between a first position and a second position wherein when in the first position the plurality of spikes formed on the first end member extend beyond the upper endface of the spacer body and the plurality of spikes formed on the second end member extend beyond the lower endface of the spacer body, and when in the second position the plurality of spikes formed on the first end member do not extend beyond the upper endface and the plurality of spikes formed on the second end member do not extend beyond the lower endface (see Col 5 lines 50-60, where a set screw #24 is used for fixing endplate #22 to the body #21, where the endplate #22 would be capable of being slidingly movable against #21 and where the spikes would extend/ not extend beyond the body #21, depending where one would secure the set screw #24, or how far one would want to thread #22 against the body #21).

Regarding **Claim 26**, Rabbe et al teaches fastening means (#24) for securing the first and second end members to the intervertebral spacer body in the first position.

However, Rabbe et al does not specifically disclose that the end members are non-rotatable movable with the spacer body.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to not have the threads of Rabbe et al, wherein the end member would be capable of non-rotatably slidably movable between a first and second position

(where the end member would still be held in place by screw #24), since it has been held that omission of an element and its function in a combination where the remaining elements perform the function as before involves only routine skill in the art. *In re Karlson*, 136 USPQ 184

Furthermore, Schonhoffer discloses a similar device (as seen in Fig 4), where an body and an end member is non-rotatably slidably moveable (see Col 3 lines 35-40), where the components are secured together using a screw (#10 see Col 4 lines 10-13)).

It would also have been obvious to one having ordinary skill in the art at the time the invention was made to remove the threads of Rabbe et al to allow for non-rotatably, slidable movement as taught by Schonhoffer because non-rotatably, slidable movement applies a known technique to a known device ready for improvement to yield predictable results of adjusting the length between intervertebral implants (see Col 3 line 1-5, and see Col 3 line 35-40).

8. **Claims 27-29, 31** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbe et al US 5,776,198 and Schonhoffer US 6,015,436, as applied to claim 25 above, and in further view of Castro et al US 6,899,734.

Rabbe et al and Schonhoffer discloses the claimed invention as discussed above but does not specifically disclose one or more elastically deformable projections extending from the inner surface, the elastically deformable projections engaging the intervertebral spacer body when the end member is in the first position so that the position of the end member with respect to the spacer body is secured, wherein the one

or more elastically deformable projections are hook-type members, the elastically deformable projections are integrally formed with the end member, wherein the intervertebral spacer body includes one or more recesses for engaging the one or more elastically deformable projections

However, Castro et al discloses a similar device (as seen in Fig 3a) with an end member (#40) includes a top surface, a bottom surface, an internal bore (as seen in Fig 3a) and one or more elastically deformable projections (#48) extending from the inner surface, the elastically deformable projections engaging the intervertebral spacer body when the end member is in the first position so that the position of the end member with respect to the spacer body is secured, wherein the one or more elastically deformable projections are hook-type members, the elastically deformable projections are integrally formed with the end member, wherein the intervertebral spacer body (#12) includes one or more recesses (#23 as seen in Fig 1) for engaging the one or more elastically deformable projections (see Fig 1 and Fig 3a and Col 4 lines 45-53, which disclose hook type members, semi-resilient detents #48, which can easily be snapped into recess #23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rabbe et al to include the deformable projections (#48) and the recess (#23) of Castro et al, as disclosed above because the deformable projections (detents #48) with a corresponding recess is a simple substitution of one known element, known in the art, for another to secure an end plate onto an intervertebral spacer and is an easy way for a surgeon to simply "snap" the

endplate into place (see Col 4 lines 45-53). (The examiner also notes that the holes (#28) of Rabbe et al would also be capable of locking in deformable projections (#48) of Castro et al, if one would so choose to and properly size the projections).

9. **Claim 30** is rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbe et al US 5,776,198, Schonhoffer US 6,015,436, and Castro et al US 6,899,734, as applied to Claim 18 above, in further view of Fortier US 6,106,539.

Rabbe et al and Castro et al disclose the claimed invention with a deformable projection, as recited above, but does not specifically disclose the spacer body includes a shoulder for engaging one or more elastically deformable projections.

However Fortier discloses a similar deformable projection (#28c as seen in Fig 7) with a shoulder (#34c) on the body to which it is connecting to.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the spacer of Rabbe et al to include a shoulder (#34c) as taught by Fortier because a shoulder provides a stop means for a detent mechanism (see Col 2 lines 37-39).

10. **Claim 32** is rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbe et al US 5,776,198 in view of Schonhoffer US 6,015,436.

Rabbe et al discloses a method of implanting an intervertebral implant into an intervertebral disc space between upper and lower vertebrae, the method including the steps of:

providing an intervertebral implant (as seen in Fig 3) having an intervertebral spacer body having an upper endface and a lower endface (the upper and lower endfaces of #21) for contacting the upper and lower vertebrae, respectively;

and first and second end members (#22 respectfully as seen in Fig 3), wherein the first and second end members are slidably disposed on the intervertebral spacer body, the first and second end members including a plurality of spikes (#120) formed on a surface thereof;

inserting the intervertebral implant into the intervertebral disc, so that the upper endface formed on the invertebral space body contacts the upper vertebra and the lower engages formed on the invertebral spacer body contacts the lower vertebra;

moving the first and second end members with respect to the intervertebral spacer body so that the plurality of spikes engage the upper and lower vertebrae, respectively; and

securing the first and second end members with respect to the intervertebral spacer body (see Col 5 lines 50-60, where a set screw #24 is used for fixing endplate #22 to the body #21, where the endplate #22 would be capable of being slidably movable against #21 and where the spikes would extend/ not extend beyond the body #21, depending where one would secure the set screw #24 or how far one would want to thread #22 against the body #21).

However, Rabbe et al does not specifically disclose that the end members are non-rotatable movable with the spacer body.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to not have the threads of Rabbe et al, wherein the end member would be capable of non-rotatably slidably movable between a first and second position (where the end member would still be held in place by screw #24), since it has been held that omission of an element and its function in a combination where the remaining elements perform the function as before involves only routine skill in the art. *In re Karlson*, 136 USPQ 184

Furthermore, Schonhoffer discloses a similar device (as seen in Fig 4), where an body and an end member is non-rotatably slidably moveable (see Col 3 lines 35-40), where the components are secured together using a screw (#10 see Col 4 lines 10-13)).

It would also have been obvious to one having ordinary skill in the art at the time the invention was made to remove the threads of Rabbe et al to allow for non-rotatably, slidable movement as taught by Schonhoffer because non-rotatably, slidable movement applies a known technique to a known device ready for improvement to yield predictable results of adjusting the length between intervertebral implants (see Col 3 line 1-5, and see Col 3 line 35-40).

With regards to the lower and upper endfaces contacting the lower and upper vertebra, respectfully, (see Col 8 lines 13-20, where the implant is inserted between in the space and proper orientation of height is adjusted) the examiner notes that it would have been obvious that the endfaces would contact the vertebra depending on the patient's needs and anatomy and since the endplates are adjusted to accommodate the patient.

Response to Arguments

11. Applicant's arguments with respect to claims 16-32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jan Christopher Merene/
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733